(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 709 109 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
01.05.1996 Bulletin 1996/18

(51) Int. Cl.[6]: **A61M 25/01**

(21) Application number: **95203094.8**

(22) Date of filing: **21.09.1990**

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **22.09.1989 US 411339**

(62) Application number of the earlier application in accordance with Art. 76 EPC: **90310354.7**

(71) Applicant: **CARDIOMETRICS, INC.**
Mountain View California 94043 (US)

(72) Inventors:
- **Christian, Jeffrey J.**
  San Jose, California 95123 (US)
- **Segal, Jerome**
  Palo Alto, California 94306 (US)
- **Corl, Paul D.**
  Palo Alto, California 94303 (US)
- **Williams, Ronald G.**
  Menlo Park, California 94025 (US)
- **Hasse, Wayne C.**
  Acton, California 01720 (US)

(74) Representative: **Cross, Rupert Edward Blount et al**
BOULT, WADE & TENNANT
27 Furnival Street
London EC4A 1PQ (GB)

Remarks:
This application was filed on 13 - 11 - 1995 as a divisional application to the application mentioned under INID code 62.

(54) Joint construction for a medical guide wire

(57) A joint construction for a medical guide wire joining a tubular member (282 or 331) to a helical coil (288) has an elongate element extending therethrough. The tubular member has an outside diameter no greater than the outside diameter of the coil. A wall of the tubular member defines a passage extending through the tubular member and has an exterior surface. The tubular member has an end portion with a helical recess (286 or 333) formed therein extending through the outer surface to form a helical thread. The helical coil has a passage extending therethrough and an end portion threaded into the helical recess which fixedly secures the coil to the tubular member so that the passage in the tubular member and the passage in the coil are in alignment.

EP 0 709 109 A2

Description

The present invention relates to a joint construction for a medical guide wire. The guide wire may be for use in measuring a characteristic of liquid flow in a vessel, and in particular may be a guide wire for blood flow velocity measurements in a vessel.

According to the present invention there is provided a joint construction for a medical guide wire joining a tubular member to a helical coil having an elongate element extending therethrough, the tubular member having an outside diameter no greater than the outside diameter of the coil and having a wall defining a passage extending therethrough and having an exterior surface, characterized in that the tubular member has an end portion with a helical recess formed therein extending through said outer surface to form a helical thread, said helical coil having a passage extending therethrough and having an end portion threaded into the helical recess to fixedly secure the coil to the tubular member so that the passage in the tubular member and the passage in the coil are in alignment.

Embodiments of the present invention will now be described by way of example only and with reference to the accompanying drawings.

Figures 1 through 5 and the description associated therewith are disclosed in European Patent Application No. 0286359 published on October 12th, 1988 and have been deleted from this application since the subject matter thereof is not being claimed;

Figure 6 is a side elevational view of a guide wire;

Figure 7 is an enlarged cross sectional view of the distal extremity of the guide wire shown in Figure 6;

Figure 8 is a view taken along the lines 8-8 of Figure 7;

Figure 9 is a cross-sectional view taken along the line 9-9 of Figure 7;

Figure 10 is a side elevational view of another embodiment of a flexible elongate element in the form of a guide wire having a coaxial construction;

Figure 11 is a cross-sectional view of the distal extremity of the guide wire shown in Figure 10;

Figure 12 is a cross-sectional view of the distal extremity of another guide wire which is particularly useful when electrical noise problems are encountered;

Figure 13 is a cross-sectional view similar to Figure 12 showing another embodiment of a guide wire;

Figure 14 is a cross-sectional view similar to Figures 12 and 13 showing another embodiment of a guide wire;

Figure 15 is a side elevational view of another embodiment of a guide wire provided with a protective covering to protect the same from attacks by blood and other saline solutions;

Figure 16 is an enlarged cross-sectional view taken along the lines 16-16 of Figure 15;

Figure 17 is an enlarged cross-sectional view taken along the lines 17-17 of Figure 15;

Figure 18 is a partial view partially in cross-section of an embodiment of a guide wire utilizing screw joints;

Figure 19 is a cross-sectional view taken along the line 19-19 of figure 18.

Figure 20 is a cross-sectional view taken along the line 20-20 of Figure 18;

Figure 21 is a cross-sectional view taken along the line 21-21 of Figure 18;

Figure 22 is a view of a portion of a guide wire which is partially in cross-section showing the use of an intermediate screw joint;

Figure 23 is a cross-sectional view taken along the line 23-23 of Figure 22; Figure 24 is an elevational view of an intermediate screw joint used in the guide wire shown in Figures 22 and 23.

A guide wire 101 is shown in Figures 6-9 and is comprised of a flexible elongate element 102 which can be in the form of a hypo tube 102 having a suitable outside diameter as, for example, 0.41mm (0.016 inches), and having suitable wall thickness as, for example, 0.051mm (0.002 inches). In order to provide additional rigidity and torqueability for the guide wire 101, a core wire 103 formed of a suitable material such as stainless steel is provided. The core wire 103 can have a suitable diameter as, for example 0.20mm (0.008 inches) and extends through the hypo tube 102. Its distal extremity 104 is tapered for a distance of approximately 15 centimeters from a diameter of 0.20mm (0.008 inches) to a diameter of 0.076mm (0.003 inches). The distal extremity 104 extends beyond the hypo tube 102 and extends into a coil spring 106 which is secured to the hypo tube 102 in an appropriate manner such as by soldering. The coil spring 106 is formed of two parts, a part 106a which is formed of stainless steel and the other part 106b of a more opaque material such as a palladium alloy or other material as described in United States Letters Patent No. 4,538,622. At the region where the two portions 106a and 106b are screwed together, the spring is bonded to the core wire 103 by solder or an epoxy 107. A safety wire or shaping ribbon 108 is provided. It is formed of a suitable material such as stainless steel ribbon and has a cross-sectional dimension of 0.025mm x 0.076mm (0.001 inches x 0.003 inches). The safety ribbon or shaping ribbon 108 extends from the solder or epoxy joint 107 to the distal extremity 109 of the coil spring 106. A transducer 111 of a suitable type as, for example, a piezoelectric crystal of the type hereinbefore described is carried by the distal extremity 109 of the coil spring 106 and is secured thereto by suitable means such as a tungsten-oxide loaded epoxy 112. As can be seen, the shaping wire 108 extends into the epoxy 112. Front and rear contacts 116 and 117 are provided on the transducer 111 and are connected to a two conductor wire 118 which extends rearwardly and interiorly of the spring 106 and extends into the hypo tube 102 between the core wire

103 and the interior of the hypo tube 102. The wire 118 extends out the distal extremity 119 of the hypo tube 102 and is connected to a male connector 121. The distal extremity of the hypo tube 119 can be secured to the core wire by suitable means such as an epoxy. The surface of the crystal serving as a transducer 111 can be coated with a suitable protective material such as a urethane coating 122. As shown, the spring 106 can extend for a predetermined distance, as for example, 1.5 centimeters beyond the tapered distal extremity 104. The portion 106b of the coil 106 can have a suitable length as, for example, 3 centimeters.

The guide wire 101 can have a suitable overall length, as for example, 175 centimeters. The crystal transducer 111 can have a suitable diameter as, for example 0.49mm (0.019 inches).

By providing a guide wire of this size, it is possible to utilize a guide wire in connection with conventional balloon dilatation catheters to perform angioplasty procedures.

The transducer 111 would have a suitable frequency as, for example, 10 MHz and a diameter of 0.5 millimeters to produce a beam divergence of approximately 20° which will produce a far field uniform beam capable of insonifying a 2.5 millimeter vessel at a range gate depth of 10 millimeters. Thus again, it can be seen that this makes possible instantaneous blood flow velocity measurements before and after an angioplasty procedure.

In Figures 10 and 11 another embodiment of the flexible elongate transducer carrying device is shown in the form of a guide wire 131. The guide wire 131 consists of a flexible elongate element 132 which serves as the main shaft for the guide wire 131. The element 132 is formed of a suitable material such as a stainless steel tubing often called a hypo tube. This tube as hereinafter described performs a number of functions. It serves as a torsional member, as a conductor and also as a conduit for carrying other conductors internally. The hypo tube has a suitable outside diameter as for example 0.42mm (0.0165 inches) and a suitable wall thickness, as for example, 0.051mm (0.002 inches) to provide an inside diameter of 0.32mm (0.0125 inches). The element 132 can have a suitable length, as for example 150 to 175 centimeters.

A core wire 133 is disposed within the flexible elongate element 132 and is also formed of a suitable material such as stainless steel and provides additional stiffness for the main shaft of the guide wire 131. The core wire 133 can be solid and has an outside diameter ranging from 0.17 to 0.22mm (0.0065 to 0.0085 inches) and has a length which sets so that it extends beyond the distal extremity 134 of the flexible elongate element 132. The forwardmost extremity of the core wire 136 is provided with tapered portions 136a and 136b. Portion 136a has a length of approximately 4 centimeters and which tapers down from the exterior dimension of the core wire to a dimension of 0.13mm (0.005 inches). The portion 136b has a length of approximately 1/2 centimeter and tapers down from 0.13mm (0.005 inches) to 0.051mm (0.002 inches).

An insulating sleeve 141 is formed of a suitable insulating material such as a polyimide tubing. The polyamide tubing forming the sleeve 141 forms a relatively tight fit with the exterior surface of the core wire 136 and fits within the hypo tube serving as the flexible elongate element 132. The sleeve 141 serves to insulate the stainless steel core wire 136 from the hypo tube serving as a flexible elongate element 132 so that they can serve as separate and independent electrical conductors.

The insulating sleeve 141 is formed of two portions 141a and 141b. The portion 141a extends to near the distal extremity 134 of the flexible elongate element or tubing 132. The other portion 141b extends over the forward extremity of the core wire 136 and in particular over the tapered portion 136a and has its proximal extremity seated within the flexible tubing 132 so that it abuts the portion 141a. The portion 141b can be formed of the same material as portion 141a and can have the same wall thicknesses and radial dimensions.

Flexible coil means 146 is secured to the distal extremity 134 of the flexible tubing 132 and consists of a coil 147 formed of a suitable material such as stainless steel wire with the coil being formed of stainless steel wire having a diameter of 0.051 to 0.076mm (0.002 - 0.003 inches) and a coil 148 which is formed of a material which is more radiopaque than stainless steel, as for example, a palladium alloy also formed of wire having a diameter of 0.051 to 0.076mm (0.002 - 0.003 inches).

A cylindrical crystal 151 which serves as a Doppler transducer is mounted on the distal extremity of the coil 148. Means is provided for establishing electrical contact with the crystal 151 and consists of an insulated conductor 152 which is connected to the front or distal face of the crystal 151 and extends rearwardly within the interiors of the coils 148 and 147 where it is connected to the distal extremity 134 of the flexible tubing 132. This conductor 152 is provided because it has been found that the resistance provided by the stainless steel coil 147 and the paladium alloy coil 148 is greater than desired. Conductor means is also provided for establishing electrical contact with the rear side of the crystal 151 and consists of a conductive braid 153 which is formed of three stands 156, 157 and 158 of an insulated beryllium copper wire, the wire itself having a diameter of 0.025mm (0.001 inches). Braiding of the wire is used rather than twisting of the wire because this gives a greater flexibility to the wires while retaining a very high tensile strength. For example, the beryllium copper wire has a tensile strength approximately twice that of pure copper wire. The conductive braid 153 is secured to the rear side of the crystal 151 by a conductive adhesive joint 161 of a conventional type. As shown in Figure 11, the braid extends around the distal extremity of the core wire 136 and is secured to the core wire 136 intermediate the ends of the tapered portion 136a by a conductive adhesive joint 162.

An additional adhesive joint 163 is provided between the proximal extremity of the coil 147 and the distal extremity of the flexible tubing 134 and the insulating sleeve 141. Another adhesive joint 164 is provided between the proximal extremity of the sleeve portion 141a and the distal extremity of the sleeve portion 141b and the exterior surface of the core wire 136. Similarly, an adhesive joint 166 is provided between the proximal extremity 133 of the flexible elongate member 132 and the proximal extremity of the insulating layer 141a. Similarly, an adhesive joint 167 is provided between the proximal extremity of the sleeve portion 141a and the exterior surface of the core wire 136. The adhesive joints 163, 164, 166 and 167 can be formed of any suitable conventional non-conductive adhesive. These adhesive joints ensure that torsional force applied to the outer flexible stainless steel tubing 132 is transferred to the insulating sleeve 141 and to the core wire 136 so that torsional forces applied to the guide wire are transferred to the distal extremity of the guide wire.

A flexible conductor cable 171 is connected to the proximal extremity of the guide wire and carries conductors 172 and 173 within insulating material 174. Conductor 172 is secured to the proximal extremity of the flexible tubing 132 whereas conductor 173 is secured to the proximal extremity of the core wire 136. The cable 171 is terminated in a connector 176.

A lens 181 is mounted on the front surface of the crystal 151. The lens can be formed of a suitable material such as thermosetting No. PC12 epoxy supplied by Dexter Hysol, 10501 East Don Julien Road, City of Industry, CA 91746. The lens is molded or machined to be approximately hemispherical in shape, and is secured to the crystal 151 by a conventional adhesive which provides excellent acoustical properties. Alternatively, the lens can be formed via surface tension so that it takes a natural hemispherical shape. This is due to the natural forces exerted on the droplet of adhesive which forms the lens. The force exerted causes the viscous material to assume a hemispherical shape, exactly in the way that a droplet of water beads upon a newly waxed automobile. Formation in this manner provides an excellent exterior high quality lens surface finish which facilitates the formation of a beam pattern without substantial scattering of ultrasonic energy. This hemispherical lens creates a very uniform diverging beam which extends over approximately 90° thereby providing a uniform insonification across the vessel being examined.

The connector 176 can be connected to a flow meter of the type hereinbefore described to provide an indication of flow being measured by the Doppler crystal 151.

With a guide wire of the type shown in Figures 10 and 11, it is possible for the physician performing a coronary angioplasty procedure to insert the guide wire in place of the guide wire utilized in the angioplasty and dilatation catheter to make a blood flow velocity measurement prior to the dilatation of the occlusion and immediately after the dilatation of the occlusion to ascertain the improvement in blood flow velocity. The guidewire-type construction for the flow measurement device facilitates making of pre and post stenosis flow measurements.

It is also possible to utilize the present guide wire to introduce the angioplasty dilatation catheter even though this is not a recommended procedure. This can be accomplished by loading of the guide wire into the angioplasty dilatation catheter and then introducing the guide wire followed by the dilatation catheter into the vessel of the patient.

It has been found that the guide wire shown in Figures 10 and 11 has excellent mechanical properties. The concentricity or coaxial construction provided in the guide wire gives a high degree of torqueability and steerability to the device. The construction of the tip of the guide wire makes it very floppy so that it can be readily steered into small vessels in the cardiovascular system. The conductive braid in addition to serving as a conductor provides a safety wire to prevent the tip of the guide wire from becoming separated from the main shaft of the guide wire. The beryllium copper conductive braid has high tensile strength while still giving high flexibility to the tip of the guide wire. It also gives good conductivity with a high resilience.

Still another embodiment of a guide wire is shown in Figure 12 which is particularly useful in the event significant electrical noise problems are encountered which require shielding of the conductors utilized in the guide wire.

The guide wire 191 shown in Figure 12 is constructed in a manner quite similar to that shown in Figures 10 and 11. Thus it is provided with stainless steel tubing 132, a core wire 136 and coil means 146. It is also provided with a Doppler crystal 151 and a lens 181. In order to achieve a shielding to isolate the conductors connected to the crystal 151 from electrical noise, a third electrical conductor 192 is provided which is in the form of a flat wire helically wound around the core wire 136. This third electrical conductor 192 can be an insulated wire which is wrapped around the core wire 136 or alternatively it can be embedded in an insulating material 193 as shown in Figure 12 so that it is insulated from the core wire 136 and also insulated from the flexible tubing 132. A conductor 152 is connected to the helical wrapped conductor 192. The conductor 152 can be connected to the front side of the crystal 151 as described in connection with the embodiment shown in Figures 10 and 11 whereas the rear side of the crystal 151 is connected by the conductive braid 153 to the core wire 136 in the manner hereinbefore described. With this being the case, the outer stainless steel tubing 132 can serve as a grounded shield for shielding the conductors 192 and the core wire 136 from external electrical signals and thereby prevent distortion of the signal received from the crystal 151 from extraneous sources. Thus it would only be necessary that the cable 171 be provided with three conductors rather than two conductors shown in Figures 10 and 11.

It can be seen that the guide wire shown in Figure 12 can be utilized in the same manner as described in

the previous embodiments. Although it typically is not utilized for introducing a dilatation catheter into the coronary vessel once the dilatation catheter is in place and the guide wire serving as the flow velocity probe is in place, it may be used to advanced the dilatation catheter from one stenosis to the next. It is for that reason that the torsional capabilities of the guide wire are important because it facilitates using it as a steerable guide wire and to advance the dilatation catheter from one stenosis to the next. It is also important that the guide wire have a relatively flexible tip so that it will not cause trauma in the vessel in which it is advanced.

Still another embodiment of the guide wire is shown in Figure 13 in which the flexible tubing 132 or the core wire 136 are not utilized as conductors. In this embodiment the guide wire 194 includes an additional conductor 196 which is connected to the rear side of the Doppler crystal 151. This wire 196 with the wire 152 which is connected to the front side of the crystal 151 are connected to a flat conductive cable comprising multiple wires in the form of two wires 296 and 297 which are connected respectively to the conductors 152 and 196. This relatively flat multi-conductor cable 196 is wrapped in a helical fashion around the core wire 136 and is connected to the cable 171. The adhesive joints 163 and 166 are utilized to establish torsional transmitting capabilities between the tubing 132 and the conductor cable 196 as well as to the core wire 136. In this embodiment, the braid 153 is made of stainless steel wire and merely serves as a safety wire and does not serve as a conductor. Thus in this embodiment it can be seen that the stainless steel tubing 132 can also serve as a shield to keep out extraneous electrical signals from the conductors 197 and 198 to ensure that a noise free signal is received from the Doppler crystal 151.

Another embodiment of the guide wire is shown in Figure 14. The guide wire 201 shown in Figure 14 includes a flexible elongate member 202 in the form of stainless steel hypodermic tubing. The member or tubing 202 is provided with a distal extremity 203. The tubing 202 has a cylindrical passage 204 extending therethrough and has a core wire 206 disposed therein. The core wire 206 has a diameter slightly less than the interior diameter of the passage 204 and does not extend through the length of the tubing 202. As shown particularly in Figure 14, the core wire 206 terminates shortly after the distal extremity of the tubing 202 and is secured therein by suitable means such as a solder joint 207. The core wire 206 is provided with a shaft portion 206a which has a substantially continuous diameter ranging from 0.15 to 2.29mm (0.006 to 0.009 inches) and preferably approximately 0.20mm (0.008 inches). The shaft portion 206a has a length of approximately 27 centimeters. The core wire is also provided with a tapered portion 206b which is tapered from 0.20mm (0.008 inches) to 0.13mm (0.005 inches) and has a length of approximately 2 centimeters. The core wire is provided with an additional tapered portion 206c which is tapered from 0.13mm (0.005 inches) to 0.051mm (0.002 inches) and has a length ranging from 1 to 2 centimeters. The core wire 206 is also provided with a cylindrical end portion 206d which has a diameter of 0.051mm (0.002 inches) and has a suitable length such as 5 millimeters.

Coil means 208 of the type hereinbefore described is provided which is secured to the distal extremity of the flexible elongate member formed by the tubing 202. The coil means consists of a length of stainless steel coil 209 and a length of palladium alloy coil 211 with the stainless steel coil 209 being secured to the core wire 206 and to the distal extremity of the tubing 202 by a solder joint 207. A Doppler crystal 212 is secured to the distal extremity of the palladium alloy coil 211 by a solder joint 213. Two conductors 216 and 217 are secured to the front and rear sides of the Doppler crystal 212 and extend through the passage 204 and beyond the proximal extremity of the tubing 202 by extending through the coil means 208 and between the interior of the tubing 202 and the outside diameter of the core wire 206. A flexible braid 221 is provided which is embedded in the solder joint 213 and extends proximally from the distal extremity of the coil means 208 and over the distal extremity of the core wire 206 to the region where the coils 209 and 211 abut and into a solder joint 222 which bonds the abutting regions of the coils 209 and 211 and the proximal extremity of the braid 221. The flexible braid 221 differs from the braid hereinbefore described in that it need not be a good conductor. Thus, stainless steel can be utilized for such a braid. A lens 226 is mounted on the Doppler crystal 212 and serves the same purpose as the lens 181 hereinbefore described.

In this embodiment of the guide wire, the conductors 216 and 217 provide the connections to the crystal making it unnecessary for either the tubing 202 or the core wire 206 to serve as conductors.

The guide wire shown in Figure 14 has a number of advantages. It has greater flexibility at its distal extremity, while providing the desired degree of stiffness in the area adjacent to the distal extremity and permitting the guide wire to follow tortuosities in the vessels. It has good torsion capabilities facilitating its steering in the vessels. Also the construction shown makes possible the use of a larger core wire and conductor wires which do not need to be flattened.

It has been found that the torsional and flexure properties of the described guide wires are virtually equal to that of existing guide wires utilized in angioplasty at the present time. In addition, however, the described guide wires provide the desired electrical properties for supplying signals to and from the Doppler crystal. In addition, the acoustical properties that are provided by the lenses 81, and 226 provides in the guide wire a combination of torsion, flexure, electrical and acoustical properties which provide a flow probe that performs admirably under many applications and in particular, cardiovascular applications involving angioplasty. The described guide wires have the floppiness or flexure capabilities of conventional guide wires while still providing means for carrying the electrical signals to and from the Doppler

crystal. The coaxial design utilized in the guide wires shown in Figures 10-14 provides excellent torsional capabilities. In addition, the construction makes it possible to maximize the size of the stainless steel core wire. The guide wire construction also makes it possible to provide maximum electrical noise rejection while still retaining the desired flexure and torsional capabilities for the guide wire.

Still another embodiment of a guide wire is shown in Figures 15, 16 and 17. The guide wire 231 shown in Figure 15 consists of a flexible elongate member 232 in the form of stainless steel hypodermic tubing having a suitable outside diameter, as for example 0.46mm (0.018 inches) and having a wall thickness ranging from 0.058 to 0.076mm (0.0023 to 0.003 inches) and preferably a wall thickness of 0.066mm (0.0026 inches). The member or hypodermic tubing 232 can have a suitable length such as 100 to 150 centimeters. The tubing 232 is provided with a centrally disposed passage 233 extending therethrough. It is also provided with a distal extremity 234 and a proximal extremity 236. A core wire 238 of suitable material such as stainless steel is provided and has a proximal extremity 239 which is disposed within the distal extremity 234 of the hypodermic tubing 232. The core wire can have the same diameter and length as the core wire 206 provided in the embodiment shown in Figure 14. It is provided with a tapered distal extremity 241 in the same manner as with the guide wire 206.

Coil means 246 of the type hereinbefore described is secured to the distal extremity 234 of the hypodermic tubing 232 and consists of a length of a stainless steel coil 247 and a length of a palladium alloy coil 248.

A Doppler transducer or crystal 251 is secured to the distal extremity of the palladium alloy coil 248 by suitable means such as an adhesive joint 252. A pair of electrical leads 253 and 254 are provided in which the lead 253 is connected to the front surface of the crystal 251 and the lead 254 is connected to the rear surface of the crystal 251. The leads 253 and 254 can be formed of a suitable material such as 45 gauge copper wire which is provided with a covering of high temperature insulation of a conventional type which can withstand the temperature of melted solder. Thus, as shown each of the leads is provided with a conductor 256 which is circular in cross-section with an insulating covering 257 surrounding the same.

As can be seen, particularly from Figures 16 and 17, the leads 253 and 254 extend rearwardly from the crystal 251 interiorally of the coil means 246. A flexible braid 261 of stainless steel of the type hereinbefore described is provided within the coil 248 and extends rearwardly from the adhesive joint 252 and over the distal extremity 241 of the core wire 238. The flexible braid has its proximal extremity bonded to the distal extremity of the core wire 238 and to the coil means 246 by a solder joint 262. The solder joint 262, in addition, bonds together the abutting ends of the coils 247 and 248. An additional solder joint 264 is provided for bonding the proximal extremity of the stainless steel coil 247 to the distal extremity 234 of the hypodermic tubing 232 and also to form a bond with the proximal extremity of the core wire 238. A hemispherical lens 266 formed in the manner hereinbefore described is provided on the front surface of the Doppler crystal 251.

In connection with the embodiment of the guide wire shown in Figures 15, 16 and 17, special precautions are taken to ensure that the guide wire is not susceptible to attack from the fluid in which it is disposed, as for example, in blood or other saline solution. To this end, during the manufacture of the guide wire 231 and at the time that the electrical leads 253 and 254 are secured to the front and back sides of the crystal 251, a protective cover in the form of a conformal coating 268 is applied to the crystal. Such a conformal coating is typically deposited in a vacuum onto the crystal and is relatively thin, as for example, 0.0025mm (0.001 inches). Such a conformal coating can be provided on the Doppler crystal or transducer 251 and the leads attached thereto to a distance extending approximately at least two millimeters from the crystal. One material found to be satisfactory for such a protective conformal coating is Parylene, a polymeric coating, manufactured by Union Carbide.

The leads 253 and 254 are inserted through the palladium alloy coil 248 and the flexible braid is inserted into the palladium alloy coil 248. A protective tube 271 formed of a suitable material such as a polyimide is inserted into the stainless steel coil 247. The protective tube can have a suitable diameter such as 0.25mm (0.0100 inches) ID with an OD of 0.29mm (0.0115 inches). The core wire 238 is then inserted into the coils 247 and 248. The distal extremities of the palladium alloy coil 248 and of the flexible braid 261 are secured to the Doppler crystal 251 by an adhesive joint 252 formed by an ultraviolet cured adhesive. Thereafter, the solder joints 262 and 264 can be applied. The insulation on the electrical leads 253 and 254 can withstand the temperature of the melted solder. Thereafter, the entire distal extremity of the guide wire 231, after it has been assembled, is coated with a second conformal coating 272 of Parylene to provide additional protection against attack by blood and other saline solutions. Parylene has been found to be a very suitable material for use in guide wires of the present construction because it permits elongations of over 200% without affecting the integrity of the coating. By utilizing such a conformal coating, it is possible to retain the desired characteristics of the guide wire without deleteriously affecting the desired characteristics to any significant extent. Thus with a Parylene conformal coating, the springiness of the tip can be retained. A Teflon coating 274 is provided on the exterior surface of the hypodermic tubing to reduce the friction between the guide wire 231 and the catheter into which it is introduced.

The guide wire 231 shown in Figure 15 is provided with a micro-miniature connector 276 of the type which is described in US Patent No. 4961433. The details of this micro-miniature connector 276 therefore will not be described in this application. However, in general it consists of a first conductor 277 formed of a crimped core

wire and a second conductor formed by a conductive sleeve 278. One of the electrical leads 253 and 254 is connected to the first conductor 277 and the other of the electrical leads 253 and 254 is connected to the second conductor 278. As can be seen, the micro-miniature connector 276 is mounted in the proximal extremity 236 of the hypodermic tubing 232.

The guide wire construction hereinbefore described in Figures 15, 16 and 17 has numerous advantages. The hypodermic tubing 232 serves as a flexible shaft. In addition, it provides a conduit for the electrical leads 253 and 254. It also provides a high degree of torque transmission while remaining as flexible as a solid stainless steel wire so that the guide wire 231 can be readily positioned in angioplasty procedures. The flexible braid 261 prevents longitudional extension of the tip of the guide wire or, in other words, elongation of the palladium alloy coil 248 to prevent separation of the Doppler crystal or transducer from the guide wire. The flexible braid 261 formed of stainless steel maximizes tensile strength, while still permitting a high degree of flexibility in the tip of the guide wire. The use of a tapered core wire provides a smooth transition from the highly flexible tip of the guide wire to the less flexible hypodermic tube shaft. The two solder joints 262 and 264, in addition, to performing their mechanical connecting functions also increase the torque transmission of the guide wire. The use of the palladium alloy provides high radiopacity for the tip of the guide wire. Coating of the stainless steel hypodermic tubing 232 with the Teflon friction-reducing coating reduces the friction between the guide wire and the catheter in which it is used.

The spherical lens 266 which is formed by a surface tension provides a lens of natural shape which gives a wide dispersion of the ultrasound beam as, for example, an angle of 90° to obtain excellent coverage within the vessel in which the guide wire is disposed.

The micro-miniature connector 276 makes it possible to utilize the guide wire as a standard guide wire in exchanging catheters in a PCTA procedure. As hereinbefore explained, in order to protect the electrical leads 253 and 254 from the affects of blood or other substances which the guide wire may encounter a plurality of protective coatings is provided. The sheath or tube 271 formed of polyimide covers the electrical leads between the two solder joints 262 and 264 and thus protects the leads from coming in contact with blood which could seriously degrade the conductive qualities of the leads. The polymide sheath also provides mechanical insulation in that it prevents the electrical leads from chafing against and short circuiting to the stainless steel coil. In addition, the polyimide sheath 271 provides a slight amount of a desired stiffness to the guide wire in this region of the guide wire. Also, as pointed out previously, the Doppler transducer or crystal with the electrical leads attached thereto is coated with a conformal coating of Parylene which provides a durable barrier to protect the transducer and the connecting electrical leads from blood. In addition another conformal coating (not shown) of Parylene is provided after completion of assembly of the guide wire by coating the entire distal extremity approximately the last 30 centimeters. This sheath 271 and the Parylene coating protect the entire assembly from attack by blood and preserves the integrity of both the electrical and mechanical characteristics of the guide wire for indefinite periods of time and certainly for periods of time more than adequate to perform any conventional procedure, as for example, an angioplasty procedure in which such a guide wire is used.

From the foregoing it can be seen that a guide wire construction has been provided in which the portions of the electrical leads which could come in contact with blood, as for example, the portions of the leads extending through the coils are protected by the polyimide tube or sheath and the conformal coatings.

Another embodiment of the guide wire utilizing screw joints is shown in Figures 18 through 21 and is of a type which incorporates screw joints. The guide wire 281 shown in Figure 18 consists of a flexible elongate member 282 in the form of stainless steel hypodermic tubing of the same dimensions described in conjunction with the guide wires shown in Figure 15. The elongate member 282 is provided with a passage 283 extending therethrough. The elongate member 282 is provided with a distal extremity 284. A helical slot 286 is cut into the exterior surface of the distal extremity 284 and extends through the wall of the hypodermic tubing 282 to form threads. The helical slots 286 can be formed in a suitable manner such as by machining. Such a density would provide threads with a helix angle of 9.50′ and a pitch of 0.235mm (0.00926 inches). Such helical slots can be formed by utilizing a diamond dicing saw with a very thin blade having a thickness ranging from 0.038 to 0.025mm (0.0015 to 0.0010 inches) and by utilizing a helical drive mechanism to feed the distal extremity 284 into the diamond dicing saw.

Typically, the hypodermic tubing forming the elongate member 282 has an outside diameter ranging from 0.43 to 0.45mm (0.017 to 0.0178 inches) and is coated with a suitable lubricant such as Teflon to facilitate movement of the guide wire 281 in a vessel of a patient. The inside diameter of the hypodermic tubing can vary from 0.36 to 0.38mm (0.014 to 0.015 inches) to provide a wall thickness ranging from 0.038mm (0.0015 inches) to 0.064mm (0.0025 inches). The helical slot or groove 286 has a width which can range from 0.064 to 0.11mm (0.0025 to 0.0045 inches). The threads formed by slot or groove 286 have a density which can range from 2.95 to 6 per mm (75 to 150 per inch) and preferably about 4.3 per mm (108 per inch) for tubing having a diameter of 0.46mm (0.018 inches) or less.

An insulating and protective tube 287 formed of a suitable material such as polyimide is disposed in the passage 283 of the hypodermic tubing 282 and extends beyond the distal extremity 284 of the hypodermic tubing. A coil 288 formed of a suitable material such as stainless steel is threaded into the helical slots or grooves 286 and extends over the portion of the insulating tube 287

extending beyond the distal extremity 284 of the elongate member 282. This connection serves to form a screw joint 289 rather than the solder joint hereinbefore described. To provide high x-ray visibility, a palladium coil 291 is threaded into the stainless steel coil 288 as shown in Figure 18 and solder 292 is applied to provide a solder screw joint 293 between the stainless steel coil 288 and the palladium coil 291.

A screw tip 296 is provided and can be formed of a suitable material such as stainless steel and have the same dimensions as the hypodermic tubing forming the elongate member 282. THe tip can have a suitable length such as 1.27 to 1.52mm (0.050 to 0.060 inches). A helical thread or recess 297 is formed in the exterior surface of the tip 296 and receives the distal extremity of the palladium coil 291. The helical recess 297 is formed in a manner similar to the helical slots 286. However, rather than being cut all the way through as with the helical slots 286, the helical recess 297 extends only through a portion of the wall forming the tip 296. Thus, with the wall thickness of 0.10 to 0.13mm (0.004 to 0.005 inches) the recess or thread can have a depth ranging from 0.064 to 0.097mm (0.0025 to 0.0038 inches) and can be squared or have a full radius.

When the tip 296 is threaded into the distal extremity of the coil 291, the tip itself is aligned with respect to the coil 291. The tip 296 is provided with a cylindrical recess 301 at its distal extremity which opens in a forward direction. The recess 301 can have a depth ranging from 0.38 to 0.51mm (0.015 to 0.020 inches) and can have a diameter ranging from 0.39 to 0.42mm (0.0155 to 0.0166 inches). A Doppler transducer 302 and a lens 303 are disposed within the recess 301 and are adhered therein by suitable means such as an adhesive 304 disposed between the side wall of the recess 301 and the transducer 302 so that the rear of the transducer is free or in air.

A core wire 306 formed of a suitable material such as stainless steel extends through the insulating and protective tube 287 and is provided with a tapered distal extremity 307 which adjoins a shaping ribbon 308 having a rectangular configuration and which is secured to the screw tip 296 by suitable means such as solder 309. The screw tip 296 in addition to being threaded into the coil 291 also has the coil soldered to the tip. Conductive leads 311 and 312 are provided which extend within the insulating and protective tube 286 and over the core wire 306. They are connected to the front and back sides of the transducer 302 as shown particularly in Figure 18.

The entire coil assembly or means comprised of the coils 288 and 291 and the screw joint 293 and the screw tip 296 is Parylene coated in the manner hereinbefore described for the previous embodiments.

Operation and use of the guide wire 281 is the same as hereinbefore described with the previous embodiments. The advantage of the present embodiment is that the transducer 302 and the lens 303 are incorporated in an assembly which is very difficult to separate from the remainder of the guide wire. This is accomplished by placing the transducer 302 and the lens in the cup-shaped recess 301 provided at the tip of the guide wire. Tip separation is also prevented by the use of the soldered screw tip 296 configuration which is utilized for securing the tip 296 to the coil 291. An excellent mechanical joint is provided for securing the tip 296 to the coil 291. The recessing of the transducer 302 which is in the form of a Doppler crystal holds the same in place so there is no chance of the transducer 302 and the lens 303 being separated from the tip 296.

The screw joints provided in the guide wire 281 in addition to providing better mechanical connections also provides the advantage of providing strain relief transitions from the relatively stiff hypo tube forming the elongate member 282 to the flexible coil 288 used at the tip and also a similar transition between the coil 291 and the tip 296. Therefore the construction of the present embodiment provides very strong joints which have excellent tensile and bending load characteristics.

It should be appreciated that the cup-shaped recess 301 which is provided can be utilized for accommodating various types of transducers other than the Doppler crystal hereinbefore described. For example, it can be utilized for housing various types of sensors as, for example, a pressure transducer.

The same principles which have been utilized in the distal extremity of the guide wire 281 can also be utilized in the proximal extremity in which helical slots 316 are provided in the proximal extremity of the hypodermic tubing forming the flexible elongate member 282. A coil spring 317 formed of a suitable material such as stainless steel is threaded into the slots 316 as shown in Figure 18. The insulating sleeve 287 extends beyond the coil spring 317. A connector 321 is mounted in the spring 317 and extends into the proximal extremity of the hypodermic tubing 282 and is secured therein by suitable means such as an adhesive. The connector 321 is formed of a suitable conducting material such as stainless steel. It serves the same purpose as the connector 276 shown in Figure 15. In Figure 18, the proximal extremity of the connector 321 is not crimped. It can be provided with a crimp if desired of the type shown in Figure 15. If not desired, a non-crimped cylindrical connector 321 can be provided as shown in Figure 18.

In order to accommodate the conducting wires 311 and 312, the portion of the connector 321 disposed within the proximal extremity of the hypodermic tubing 282 is provided with flats 322 and 323 as shown in Figure 21.

The construction shown for the proximal extremity of the guide wire 282 has the same advantages as the construction provided on the distal extremity of the guide wire. A good mechanical connection is provided between the hypodermic tubing 282 and the coil spring 317 and the connector 321. The coil spring also provides a strain relief transition from the hypodermic tubing 282 to the connector 321.

One of the principal advantages of mounting the transducer 302 within the cup-shaped recess 301 is that

the adhesive 304 is provided on the circumference of the transducer 302 but is not provided to the rear of the transducer so that the rear or back side of the transducer 302 is exposed to air and can readily flex. This enhances the Doppler capabilities of the crystal or transducer.

It should be appreciated that with these screw type joints provided in the guide wire 281, the springs are threaded into the helices of the guide wire to provide an integrated construction. However, it should be appreciated that a non-integral construction could be provided by bonding the coil to the hypodermic tubing without threading the coil into the helices. It is believed that this is not as desirable because not as good a mechanical connection is provided. However, such a construction would provide a gradual transition in stiffness from the hypoderic tubing to the coil spring.

Another embodiment of a screw joint connection which can be utilized in the guide wire 281 is shown in Figures 22-24. As shown therein, rather than two coils 288 and 291 being threaded together as disclosed in Figure 18, they are interconnected by an intermediate screw joint 331. The intermediate screw joint 331 is formed of a length of hypodermic tubing 332 of the same type utilized for the elongate member 282 and is provided with helical recesses 333 and 334 at opposite ends which are formed in the same manner as the helical recesses 297 in the tip 296. As shown in Figure 22, the screw joint 331 is utilized for interconnecting the two coils 288 and 291 by threading the coil 288 into the helical recesses 333 and threading the coil 291 into the helical recesses 334. The conductors 311 and 312 and the shaping ribbon 308 extend through the screw joint 331 in the manner shown. From this construction, it can be seen that a strong mechanical connection with good alignment has been provided between the two coils 288 and 291. The entire assembly which is shown in Figure 22 can be Parylene coated in the manner hereinbefore described.

It is apparent from the foregoing that there has been provided a guide wire for measuring blood flow velocity in a vessel. This can be accomplished by the use of a single transducer positioned intravascularly to produce a beam of uniform insonification which encompasses the entirety of the blood vessel.

It should be appreciated that although the present invention has been described particularly for use in the measuring of blood flow velocity in a vessel, the present invention also can be utilized for measuring other liquids in other types of conduits if desired.

Claims

1. A joint construction for a medical guide wire joining a tubular member (282 or 331) to a helical coil (288) having an elongate element extending therethrough, the tubular member having an outside diameter no greater than the outside diameter of the coil and having a wall defining a passage extending therethrough and having an exterior surface, characterized in that the tubular member havs an end portion with a helical recess (286 or 333) formed therein extending through said outer surface to form a helical thread, said helical coil having a passage extending therethrough and having an end portion threaded into the helical recess to fixedly secure the coil to the tubular member so that the passage in the tubular member and the passage in the coil are in alignment.

2. A construction as in claim 1 further characterized in that the tubular member (331) has another end portion (334) with a helical recess therein extending through the outer surface of the wall to form another helical thread, another helical coil (291) having a passage extending therethrough and having an end portion threaded into said another helical thread of said another end portion of the tubular member to fixedly secure said another coil to said tubular member so that the passage in said another helical coil is in alignment with the passage in the tubular member.

3. A construction as in claim 1 further characterized in that the threads have a density ranging from 2.95 to 6 threads per mm (75 to 150 threads per inch).

4. A construction as in claim 1 further characterized in that the threads have a density of approximately 4.3 threads per mm (108 threads per inch).

5. A construction as in claim 1 further characterized in that approximately 2.5 to 5.0 threads are provided.

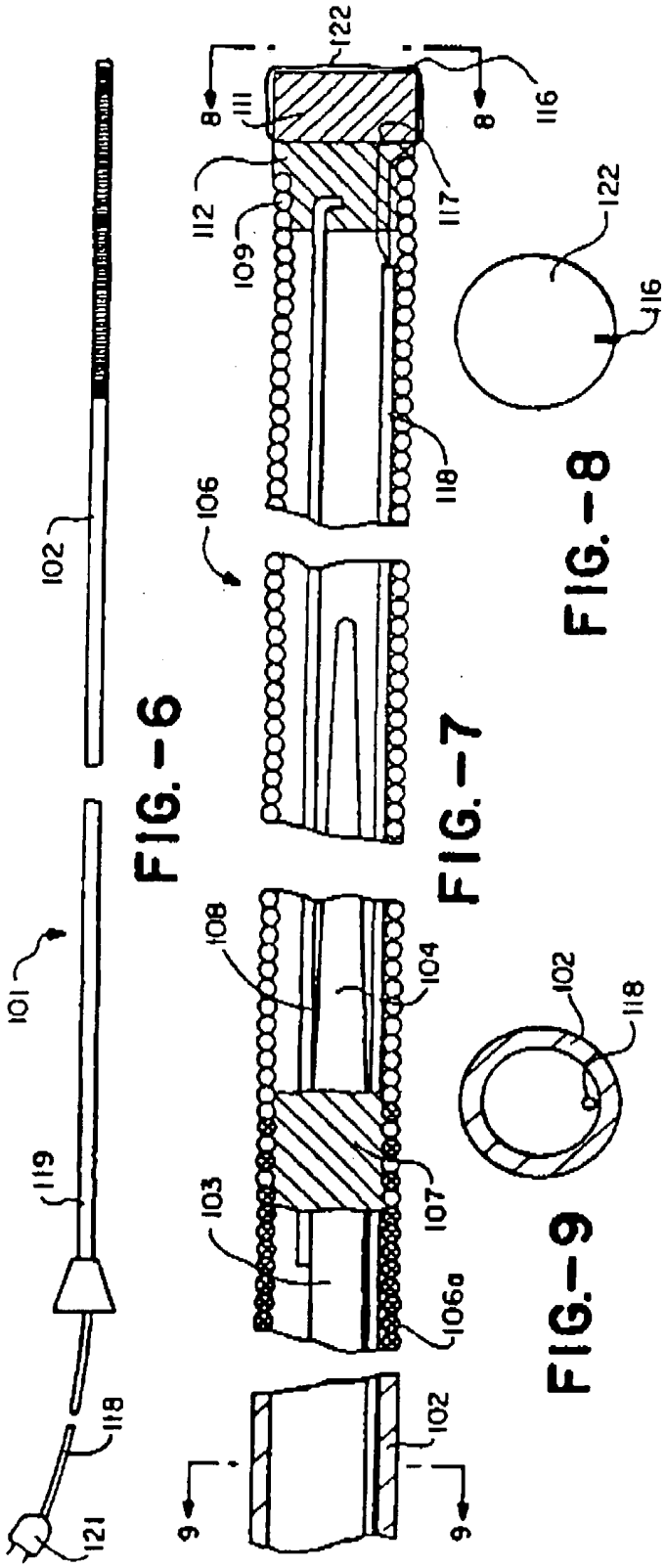
6. A construction as in claim 1 further characterized in that the threads only extend partially through the wall of the member.

7. A construction as in claim 1 further characterized in that the threads are rectangular in cross-section.

8. A construction as in claim 1 further characterized in that the coil has an outer surface and wherein the outer surface of the tubular member and of the coil are of the same size and with the helical recess being of a depth so that the outer surface of the coil spring is flush with the outer surface of the tubular member.

9. A construction as in claim 1 further characterized in that said coil is in the form of a flexible spring.

10. A construction as in claim 1 further characterized in that said coil and said another coil are in the form of flexible springs.


101
102
118
119
121
FIG.-6
122
111
112
109
117
116
106
118
FIG.-7
122
116
FIG.-8
108
104
103
107
106a
102
118
FIG.-9

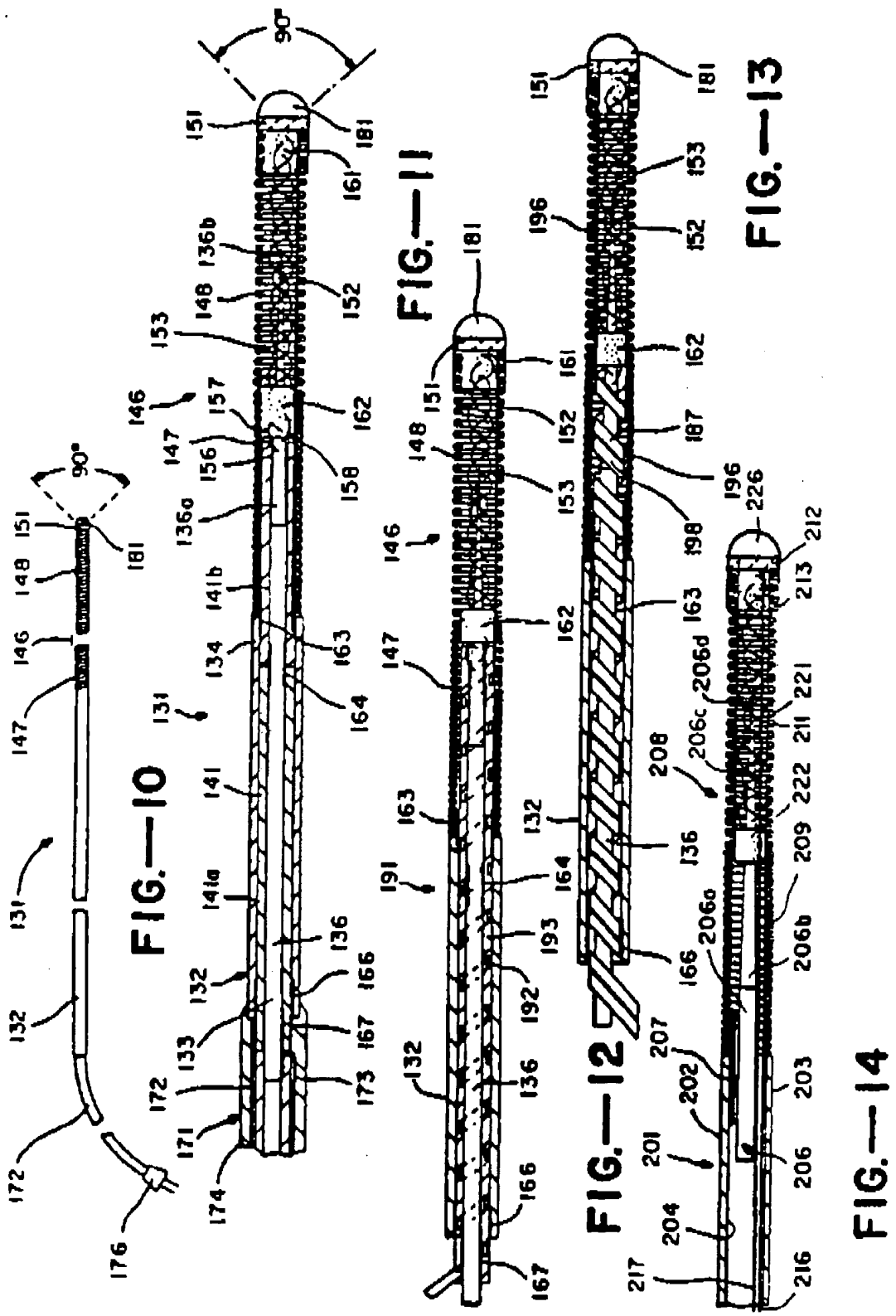


FIG.—10

FIG.—11

FIG.—12

FIG.—13

FIG.—14

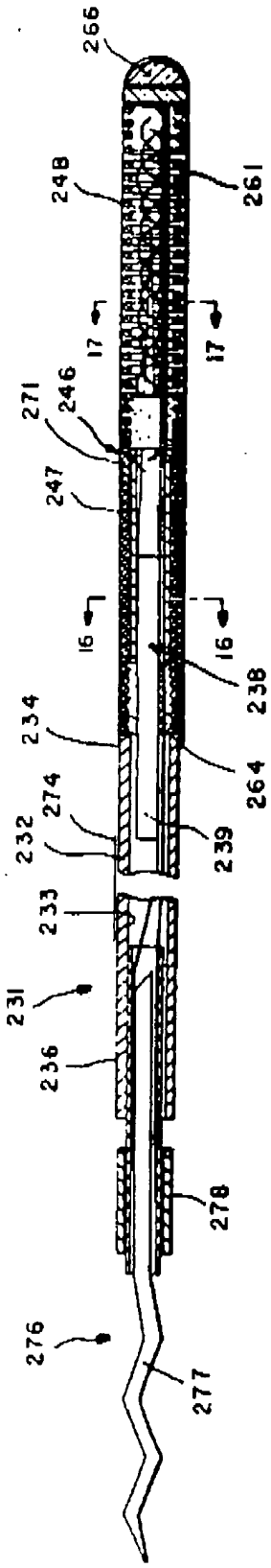


FIG.—15

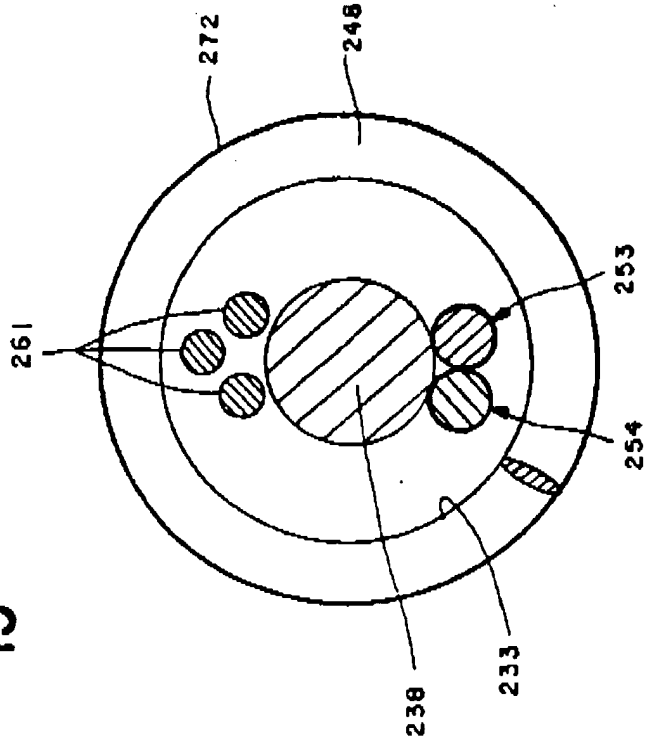


FIG.—17

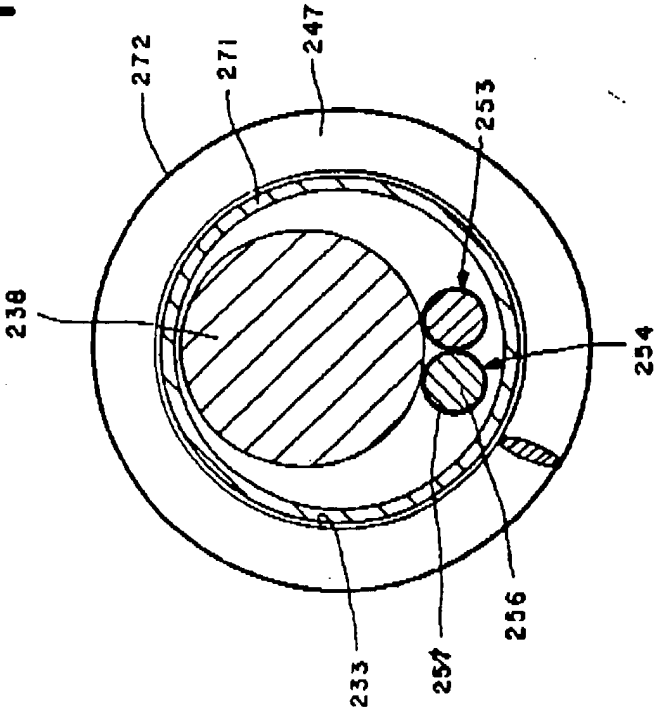


FIG.—16

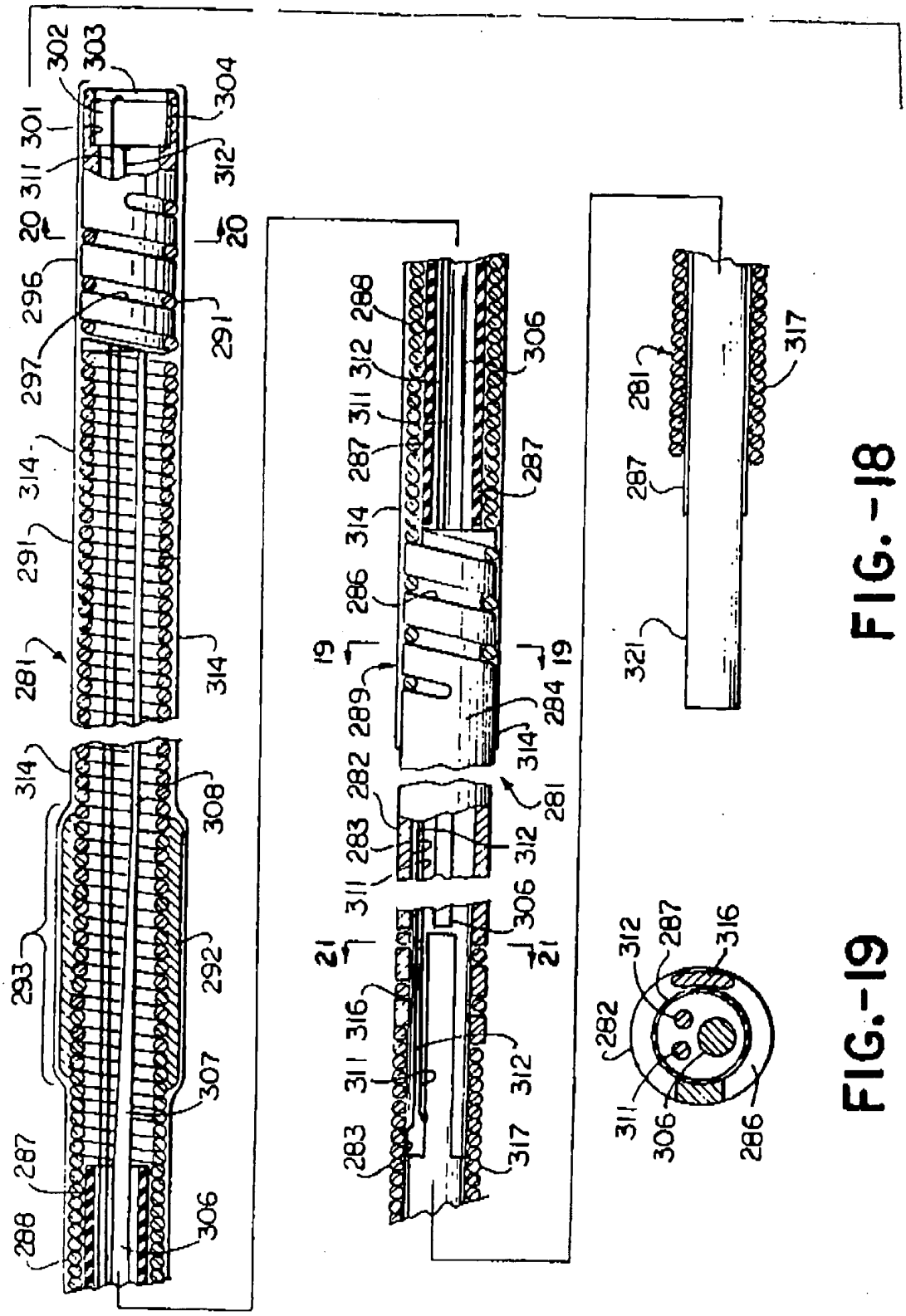

302
303
304
301
311
312
20
20
296
291
297
314
291
281
314
314
308
293
292
307
287
288
306
19
19
288
312
311
306
287
287
314
286
289
282
284
314
281
283
312
311
306
21
21
316
311
312
317
283
317
281
287
321
312
287
316
282
311
306
286

FIG.-18

FIG.-19

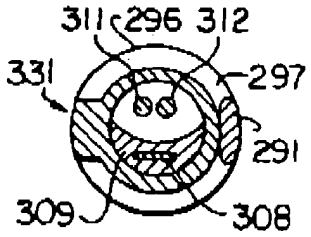


FIG.-20

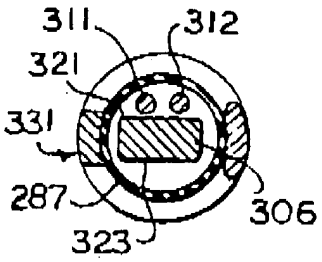


FIG.-21

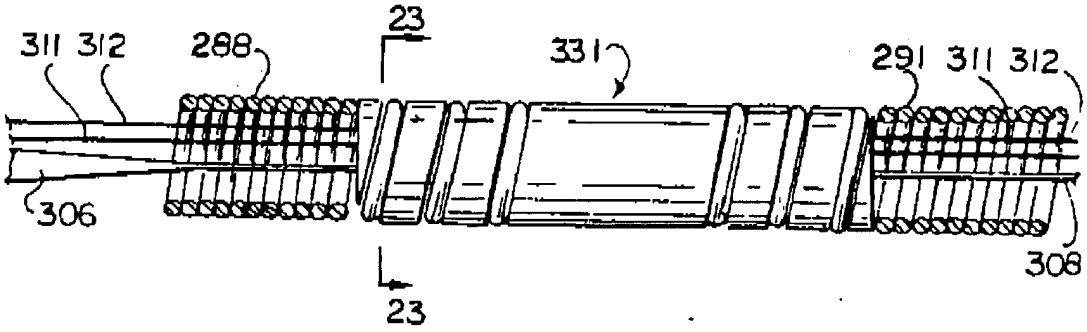


FIG.-22

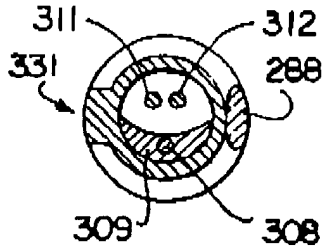


FIG.-23

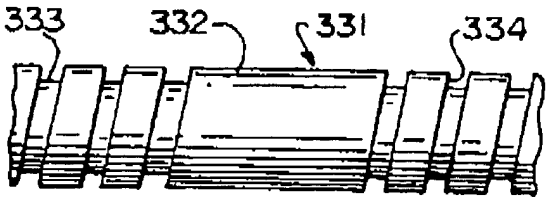


FIG.-24

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 709 109 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
08.05.1996 Bulletin 1996/19

(43) Date of publication A2:
01.05.1996 Bulletin 1996/18

(51) Int. Cl.[6]: A61M 25/01

(21) Application number: 95203094.8

(22) Date of filing: 21.09.1990

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: 22.09.1989 US 411339

(62) Application number of the earlier application in accordance with Art. 76 EPC: 90310354.7

(71) Applicant: CARDIOMETRICS, INC.
Mountain View California 94043 (US)

(72) Inventors:
- Christian, Jeffrey J.
San Jose, California 95123 (US)
- Segal, Jerome
Palo Alto, California 94306 (US)
- Corl, Paul D.
Palo Alto, California 94303 (US)
- Williams, Ronald G.
Menlo Park, California 94025 (US)
- Hasse, Wayne C.
Acton, California 01720 (US)

(74) Representative: Cross, Rupert Edward Blount et al
BOULT, WADE & TENNANT
27 Furnival Street
London EC4A 1PQ (GB)

(54) Joint construction for a medical guide wire

(57) A joint construction for a medical guide wire joining a tubular member (282 or 331) to a helical coil (288) has an elongate element extending therethrough. The tubular member has an outside diameter no greater than the outside diameter of the coil. A wall of the tubular member defines a passage extending through the tubular member and has an exterior surface. The tubular member has an end portion with a helical recess (286 or 333) formed therein extending through the outer surface to form a helical thread. The helical coil has a passage extending therethrough and an end portion threaded into the helical recess which fixedly secures the coil to the tubular member so that the passage in the tubular member and the passage in the coil are in alignment.

EP 0 709 109 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 20 3094

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP-A-0 180 348 (BAXTER) * column 8, paragraph 2 - paragraph 3; figures 1-4 *	1,2,8-10	A61M25/01
P,A	CH-A-674 943 (SARCEM) * abstract; figures *	1,2,6,8, 9	
A	US-A-2 118 631 (WAPPLER) * page 2, left-hand column, line 55 - right-hand column, line 39; figures *	1,2,8-10	
A	EP-A-0 313 836 (ADVANCED CARDIOVASCULAR SYSTEMS) * abstract; figures 1,3,6 *	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	8 March 1996	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)